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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,978	06/26/2003	John D. Dobak III	103002	6407

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EXAMINER

ROLLINS, ROSILAND STACIE

ART UNIT PAPER NUMBER

3739

DATE MAILED: 03/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/608,978

Applicant(s)

DOBAK ET AL.

Examiner

Rosiland S. Rollins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6-11 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lafontaine '735 in view of Ginsburg, et al. (US 6497721) and Amplatz et al. '751.

Lafontaine discloses a device to treat tissue comprising an outer tube (28), an inner tube (32) disposed at least partially within the outer tube and a dual balloon (14). Lafontaine teaches all of the structural components of the claims except the particular type of pump as claimed. The device of Lafontaine, however, has the structural components arranged differently such that the supply and return lumens are located on the exterior of the inner tube. Whereas the supply and return lumens of the present invention are located on the interior of the inner tube thereby causing the inlet to be defined solely by the outer tube and the inner tube. Therefore, without a showing of criticality it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the supply and return lumens of Lafontaine on the interior of the inner tube which would cause the inlet to be solely defined by the outer tube and the inner tube, since it has been held that rearranging parts of an invention involves only routine skill in the art.

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Ginsburg et al. disclose a similar device and teach that it is old and well known in the art to use a variety of different pumps to circulate the heat exchange fluid (col. 24 lines 10-14). Each of the pumps disclosed by Ginsburg et al. may be substituted one for the other. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a gear pump as the pump of Lafontaine particularly in view of the teaching of Ginsburg et al. that a substitution as such would be proper.

Lafontaine teaches all of the limitations of the claim except two radially extending tabs. Amplatz et al. disclose a balloon catheter that includes tab members to anchor the inner lumen of the catheter within the balloon while inflated. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include two tab members to anchor the inner lumen within the balloon while inflated. It would have also been obvious to one having ordinary skill in the art at the time the invention was made to make the tabs integral with device, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art.

Regarding claim 2 figure 2 illustrates the guidewire lumen, supply lumen and return lumen. **Regarding claim 6** (36) is illustrated as a marker. **Regarding claims 7-11** see col. 4 lines 49-52.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lafontaine and Ginsburg et al. further in view of Jacobsen et al. '101.

Lafontaine teaches all of the limitations of the claim except a fluid contrast media. Jacobsen et al. teach that it is old and well known in the art to provide a contrast media as an inflation fluid for a balloon catheter. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a fluid contrast media in the Lafontaine device as a means of inflating the balloon.

Response to Arguments

Applicant's arguments filed 12/30/05 have been fully considered but they are not persuasive.

Applicants argue that Amplantz fails to teach or suggest a device to treat tissue that includes the use of at least two radially extending tabs that are disposed around a circumference of the inner tube to substantially center the inner tube within the dual balloon. Applicant also argues that Amplantz does not teach or suggest using at least two tabs radially extending from the inner tube. Regarding these arguments, Examiner contends that the two tabs are not required by the claims to extend from the inner tube. The claim requires that the tabs be disposed around the circumference of the inner tube. While Amplantz does not specifically recite centering the inner tube, the disclosure inherently teaches centering of the inner tube (12) within the balloon as illustrated in figure 3.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was

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within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosiland S. Rollins whose telephone number is (571) 272-4772. The examiner can normally be reached on Mon.-Fri. 9:00 AM - 6:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Rosiland S Rollins
Primary Examiner
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